

5/PDA

Surgical Stapling Device

This invention relates to a surgical stapling device.

5     Surgical stapling devices have been in existence for many years. They are routinely used in surgical procedures mainly for the purposes of effecting a wound closure. Some of the most popular applications include closing a skin incision end-to-end or end-to-  
10    side anastomosis of internal (generally tubular) vessels such as the large bowel, etc. Current staplers are designed to deliver one or more staples in a serial fashion or a number of staples in one shot. Skin staplers, for example, deliver 30 or more staples in a  
15    serial fashion. The staples are stacked within the device and during the firing operation one staple is advanced from the stack and delivered through the head of the device. During the following cycle another staple is advanced from the top of the stack and again  
20    delivered through the head of the device and so on. In one shot devices such as a bowel anastomosis stapler the staples are prearranged in a linear or circular fashion and upon activation of the device all the staples are delivered through the head. Examples of  
25    existing prior art as described above include US Patents 4,592,498, 5,289,963, 5,433,721 and 5,470,010.

The mechanism involved in forming a staple and releasing it from its forming mechanism is common to  
30    the majority of surgical stapler devices. Generally the components include an anvil, a staple closing

actuator, and a staple release mechanism. The anvil is normally positioned in front of the staple and the actuator directly behind the staple. As the actuator advances the staple against the anvil the back section 5 of the staple deforms around both ends of the anvil thereby transforming the staple from a generally U-shape to a generally rectangular shape. At this point the actuator generally retracts and the staple is released from the anvil either as a result of the anvil 10 moving out of position and allowing the staple to move forward, or alternatively ejecting the staple over the anvil thereby releasing it from the device.

There are a number of problems associated with the 15 mechanism as described above. Firstly, as the anvil is normally positioned in front of the staple it naturally becomes trapped between the back of the staple and the tissue into which it is being delivered causing the staple back to be spaced away from the tissue as 20 opposed to lying tightly on its surface. This is a particular problem in the field of vascular puncture closure when it is desirable to keep the legs of the staple as short as possible so as to avoid having the legs of the staple within the vessel lumen.

25 Secondly, the method of releasing the staple from the anvil can be both complicated and unreliable. Metal springs are normally used which eject the staple over the anvil thereby affecting its release. However, 30 should the spring fail to operate or is prohibited from

operating properly by virtue of some tissue blockage etc, the device will become trapped in-situ.

Alternative release mechanisms include mechanical means  
5 of moving the anvil so that it is no longer in the path  
of the staple as it releases from the device. Again  
this generally involves very small metal components  
with relatively small movements which can fail to  
operate thereby leaving the staple trapped within the  
10 device and attached to the tissue into which it has  
been delivered.

Therefore there is a need for an improved surgical  
stapling device which will facilitate closer  
15 approximation of the staple back onto the surface of  
the vessel into which the staple is being delivered and  
a method of deforming the staple which does not include  
the use of an anvil component and therefore will not  
require the use of other components or mechanisms to  
20 facilitate the release of the staple from the anvil.

According to the present invention there is provided a  
surgical stapling device comprising an elongate  
housing, a surgical staple slidable longitudinally  
25 within the housing towards a free forward end thereof,  
the staple having a back and two forwardly pointing  
legs, an actuator slidable forwardly within the housing  
for driving the staple towards the free end of the  
housing, means for restraining the back of the staple  
30 against forward movement beyond a predetermined point  
such that further forward movement of the actuator

bends the staple to bring the free ends of the legs towards one another to close the staple, and means for releasing the closed staple, wherein the back of the staple has a rearward extension and the restraining 5 means comprises means for restraining the extension.

In a preferred embodiment the rearward extension is rupturably joined to the back of the staple, the staple being released by forward movement of the actuator 10 beyond the point at which the staple is closed while the extension is restrained, thereby to rupture the join.

In another preferred embodiment a rearward extension is 15 created which is integral to the staple back. This rearward extension creates a slot into which one end of an extension component is connected. Once the former has formed the staple around the anvil the extension is released from the staple during rearward movement of 20 the former.

The benefits of the invention over conventional stapling devices is that, firstly, as no anvil is required the staple can be advanced forward to a 25 position where the staple back is in direct contact with the tissue being stapled. This is of particular advantage when the staple legs must remain short but the level of penetration into the tissue must be assured. Secondly, because there is no anvil component 30 involved in the delivery mechanism, there is no requirement to add additional components so as to

facilitate ejection of the staple over or around the anvil component or alternatively to move the anvil component to a position which allows the staple to advance forward and free up the device.

5

Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

10 Fig. 1 is a perspective view of a staple with a restraining plate for use in an embodiment of the invention;

15 Figs. 2(a) to 2(d) are plan views (left hand column) and equivalent sectional views (right hand column) of a stapling device according to the embodiment in successive stages of operation;

20 Fig. 3 is a perspective view of the staple and actuator assembly of Fig. 2;

Fig. 4 is a perspective view of the forward tip of the actuator of Fig. 2; and

25 Figs. 5 to 12 are perspective view of further embodiments of staple for use with a device according to the invention.

In the drawings the same reference numerals have been used for the same or equivalent parts.

30

Referring to Figs. 1 to 4, a surgical stapling device comprises an elongated housing or shaft 10 having upper and lower halves 10a and 10b defining between them a longitudinal channel 12 for slidably accommodating a 5 staple 14 and a staple closing actuator 16 (in the plan views in the left hand column of Fig. 2 only the lower housing half 10b is shown). Only the free forward end of the housing 10 is shown in the drawings, since that is where the invention lies in the present embodiment.

10 The rear end of the housing 10 is preferably formed with a pistol grip and the movement of the various components to be described may be effected by a trigger acting through a cam system. Such an arrangement is described in Irish Patent Application S2000/0722 which 15 may be readily adapted to operate the device of the present embodiment.

The staple 14 is generally U-shaped, having a back 18 and two forwardly pointing legs 20. The free ends of 20 the staple legs 20 are sharpened for ease of tissue penetration. Integral with the staple back 18 there is a rearwardly extending plate 22 which is attached to the upper edge of the centre section 18a of the staple back by a pair of narrow, relatively weak tabs 24. The 25 tabs are effectively thin metal bridges which connect the staple back to the plate 22. At the rear end of the plate 22 there is an upstanding flange 30 perpendicular to the plane of the plate 22. In this embodiment the staple 14 including the plate 22 and 30 flange 30 is made as an integral structure from stamped and bent sheet metal stock, for example, a malleable

metal or metal alloy such as stainless steel or titanium.

Adjacent to the tabs 24, at the junctions 26 between  
5 the centre section 18a and the outer sections 18b of  
the staple back on either side, and where in use the  
staple back is designed to bend through an angle of 90°  
as will be described, local deformation of the material  
of the staple is provided so as to ensure that bending  
10 takes place preferentially at those points.

The actuator 16 is an elongated rod having a forward end which is forked to provide two arms 28 separated by a recess 34. The lateral separation of the arms 28 is  
15 slightly greater than the distance between the junctions 26 on the back 18 of the staple.

The device is assembled (Fig. 2) with the actuator 16 extending longitudinally in the channel 12 with its  
20 forked end facing towards the free forward end of the housing 10. The staple 14 is positioned freely in front of the actuator 16 with its back 18 transverse to the axis of the housing 10 with the plate 22 extending rearwardly across the top surface of the actuator. The  
25 flange 30 extends up into a recess 32 in the top housing half 10a. The actuator arms 28 are behind and in alignment with the outer sections 18b of the staple back.

30 In use, both the staple 14 and the actuator 16 are initially retracted, Fig. 2(a), so that the flange 30

is adjacent the rear end of the recess 32 and the entire staple 14 is contained wholly within the housing 10. Upon operation of the trigger previously mentioned, or other operating mechanism, the actuator 5 16 is driven forwardly towards the free forward end of the housing 10. This drives the staple 14 before it by engagement of the actuator arms 28 with the outer sections 18b of the staple back.

10 At a predetermined point, Fig. 2(b), where the back of the staple is substantially level with the forward end of the housing 10, the flange 30 comes up against the front end of the recess 32. The flange 30 and front end of the recess 32 act as cooperating stop means 15 which, via the plate 22, restrain the centre section 18a of the staple back against further forward movement. Thus, as the actuator 16 continues to advance, the actuator arms 28 bend the outer sections 18b of the back of the staple forwardly through 90° to 20 bring the free ends of the staple legs 20 towards one another and deform the staple into a generally rectangular closed shape, Fig. 2(c).

At this point the base 36 of the recess 34 in the front 25 of the actuator 16 is abutting against the centre section 18a of the staple base. Now, since the plate 22 remains restrained by engagement of the stop means 30/32 further forward movement of the actuator 16 will rupture the tabs 24 thus freeing the staple from the 30 plate 22. At this point the cycle is complete.

Fig. 5 shows an alternative embodiment for the staple. It comprises a standard round wire staple 40 having a rearwardly extending restraining plate 22 with upstanding flange 30 attached to the centre section of 5 the staple back by rupturable tabs 24. The tabs may be attached to the staple back by soldering, braising, laser welding, adhesive bonding, etc. The preferred process will ensure a consistent break-off force between the tabs and the staple back.

10

Referring now to Fig. 6, another embodiment of the staple is shown which includes two staples 14 disposed spaced apart one above and each having a respective rearwardly-extending restraining plate 22 joined thereto by rupturable tabs as previously described. In 15 this case the rear ends of the parallel plates are joined by a common flange 30. In such a case the stapling device would be modified such that stop means on the housing 10 projected into the space between the 20 upper and lower plates 22 and engaged the flange 30 between them to restrain the back of the staple. The double staple could be driven by two actuators 16, one disposed above the upper plate 22 and the other below the lower plate 22, or a single actuator could be used 25 having upper and lower branches which embrace the plates 22 between them.

Fig. 7 shows another staple usable in the invention in which the centre section 18a of the staple back is 30 enlarged, for example by forming it as a disk 42, so that the centre section 18a has a much greater area in

a plane normal to the longitudinal axis of the housing  
10 than either of the outer section 18b. This  
configuration has particular application in the field  
of vascular puncture closure. The process of closing  
5 puncture holes using conventional staples may be  
enhanced using this method as the disk 42 on the staple  
back provides greater surface coverage of the puncture  
hole area thereby effecting haemostasis in a shorter  
time.

10

Fig. 8 shows a configuration which is essentially the  
double staple as described in Fig. 6 but for use in  
combination with a stapling device having a locator  
tube 44. The locator tube 44, which passes between the  
15 plates 22 through a hole (not shown) in the flange 30,  
is slidable axially within the housing 10 between a  
forward position wherein it projects beyond the free  
forward end of the housing 10 to enter a puncture site  
in a liquid-carrying vessel in a human or animal,  
20 thereby to locate the free end of the housing at the  
puncture site, and a rearward position wherein the  
locator tube is retracted into the housing. In use a  
guidewire (not shown) extends within the locator tube  
and emerges from the forward end of the tube, the tube  
25 44 being tracked along the guidewire to the puncture  
site and the guidewire and tube being retracted into  
the housing prior to closure of the staples. A locator  
tube is described in the aforementioned Irish Patent  
Application S2000/0722, and it will be clear to one  
30 skilled in the art how to modify the embodiment shown  
in Fig. 2 to incorporate such a tube. This

configuration has particular relevance in the area of vascular puncture closure.

The staple configurations shown in Figs. 6 to 8 are,  
5 like the staple shown in Fig. 1, designed so that they are easily manufactured as integral structures from sheet metal using a conventional metal stamping and bending processes.

10 The embodiment of staple shown in Fig. 9 comprises a staple essentially as described with reference to Fig. 7 but without the attached plate 22. Instead, a rearwardly extending filament 46 is attached to the rear surface of the disk 42. In use, the stapling  
15 device is adapted to trap or hold the rear end of the filament 46 so that it becomes taut at the point where the staple back is level with the front end of the housing 10 so that further advance of the actuator will bend the outer sections 18b of the staple back to close  
20 the staple as previously described. At this point the actuator may advance further forward thereby shearing or detaching the filament from the back surface of the disk 42. Alternatively, the actuator may retract while simultaneously the device releases the filament at its  
25 rear end and consequently releasing the staple from the device. Examples of the filament material are Dacron, PLA, PGA and PLGA.

In Fig. 10 a staple configuration is shown similar to  
30 that in Fig. 3 except that the rupture tabs 24 are replaced with a slotted tab 50 which engages with an

upstanding flange 52 integral to plate 22. As the former advances forward to form the staple the back is held in position by the plate 22. Once forming is complete the former component retracts while 5 simultaneously causing the plate 22 to move down disengaging the flange 52 from the staple slot 50 allowing it to separate from the stapler device.

Figs. 11 and 12 illustrate further embodiments of this  
10 principle. In Fig. 11 the flange 52 engages a band 54 which is formed integrally with an lies parallel to the back 18 of the staple. In Fig. 12 a pair of L-shaped cylindrical arms engage a channel section 58 of the staple back 18 to restrain the staple during forming.  
15 When forming is complete the former retracts while simultaneously causing the arms 56 to be pushed outwards, away from one another and out of engagement with the channel section 58.  
20 The invention is not limited to the embodiments described herein and may be modified or varied without departing from the scope of the invention.